510(k) SUMMARY K092739

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This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

C-Link Micro Imaging, Inc.
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Los Angeles, CA 90035,
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JAN 12 2010

B. Contact Person

Mary P. Gallup
Regulatory Affairs Consultant
Hantel Technologies, Inc.
Telephone: (510) 441-4017

C. Date Prepared

July 30, 2009

D. Device Name

Trade Name: C-Link Microendoscope Model S-0001 Single Light Source and D-0001 Dual Light Source
Classification Name: Endoscope and Introducer Instruments

Device Description

Like the predicate devices, the C-Link Microendoscope Model S-0001 Single Light Source and D-0001 Dual Light Source consist of a semi-rigid fiberscope with a separate irrigating outer sheath or introducer to view and assess/biopsy soft tissue.

F. Intended Use

The C-Link Microendoscope Model S-0001 Single Light Source and D-0001 Dual Light Source are intended for use by a physician for viewing an interior cavity of the human body through either a natural opening or an incision.

Substantial Equivalence

The C-Link Microendoscope Model S-0001 Single Light Source and D-0001 Dual Light Source are substantially equivalent to the Acueity ViaDuct Microendoscope and Accessories, cleared by the FDA under K011189. The design of the C-Link Microendoscope Model S-0001 Single Light Source and D-0001 Dual Light Source are similar to the predicate device insofar as intended use, principles of operation, anatomical site for viewing and sampling, safety characteristics and physical characteristics.

G. Device Testing Results and Conclusion

All necessary testing was or will be performed on the C-Link Microendoscope Model S-0001 Single Light Source and D-0001 Dual Light Source to ensure that the product is substantially equivalent to the predicate devices and to ensure that the new device does not have a significant effect on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

C-Link Micro Imaging, Inc.
% Ms. Mary P. Gallup
RegulatoryAffairs
Hantel Technologies, Inc.
721 Sandoval Way
HAYWARD CA 94544

JAN 12 2010

Re: K092739
Trade/Device Name: Microendoscope Model S-0001 Single Light Source and Model D-0001 Dual Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODF
Dated: August 31, 2009
Received: September 23, 2009

Dear Ms. Gallup:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use K092239

510(k) Number (if known): K092739

Device Name: Microendoscope Model S-0001 Single Light Source and Model D-0001 Dual Light Source

Indications For Use:

This device is to be used by a physician for viewing an interior cavity of the human body through either a natural opening or an incision.

Prescription Use __Yes____ AND/OR Over-The-Counter Use __No____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092739